

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK**

-----  
IN RE: KIND LLC "HEALTHY AND ALL  
NATURAL" LITIGATION

\_\_\_\_\_  
THIS DOCUMENT RELATES TO:  
  
ALL ACTIONS

X ECF Case

:

:

: Case No. 1:15-md-02645-WHP

:

: **DEFENDANTS KIND LLC AND**

: **KIND MANAGEMENT, INC.'S**

: **MEMORANDUM OF POINTS**

: **AND AUTHORITIES IN**

: **SUPPORT OF THEIR MOTION**

: **TO DISMISS**

:

:

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## I. INTRODUCTION AND SUMMARY OF ARGUMENT

On March 17, 2015, FDA issued a warning letter to KIND LLC. It alleged that the phrase “healthy and tasty” as part of romance language on the back of the label of some of KIND’s snack bars, shown in its actual 5.5 point font size below, was not permitted under 21 C.F.R. § 101.62(c)(2).



FDA asserted that because the bars contained more than 1 gram of saturated fat per the Reference Amount Customarily Consumed (“RACC”), the labeling violated § 101.62(c)(2).<sup>1</sup> To get there, the warning letter navigated highly technical issues relating to the multi-requirement, detailed and complex federal regulations governing “healthy.”

Immediately after FDA made its warning letter public, plaintiffs quickly filed over a dozen consumer class actions (now joined in the consolidated Complaint), claiming that consumers were deceived based on the identical theory, *i.e.*, because KIND’s bars “do not meet

<sup>1</sup> FDA alleges that use of “healthy” in the back-label romance language is “an implied nutrient content claim on the label . . . of a food,” triggering a requirement that “the food . . . is ‘low in saturated fat’ as defined in 21 C.F.R. § 101.62(c)(2).” Dkt. 52-1, Ex. A at 1, 2. KIND contends that the phrase “healthy and tasty” does not constitute an implied nutrient-content claim because the use of the term “healthy” is not in “in association with an explicit or implicit claim or statement about a nutrient (e.g., ‘healthy,’ contains 3 grams of fat),” 21 C.F.R. § 101.65(d)(1)(ii), as is necessary to implicate the “low saturated fat” requirements set forth in § 101.62(c)(2). KIND and FDA continue to discuss the matter.

the necessary requirements under federal law to be labeled as ‘healthy.’” Compl. ¶ 5. Appended to their copy-cat “healthy” allegations, plaintiffs also make claims against almost every product sold by KIND based on the “all natural” statement on the labels. That is misleading, according to plaintiffs, because KIND products may contain allegedly synthetic or artificial ingredients or may contain GMOs.

Plaintiffs’ Complaint demonstrates how follow-on, lawyer-driven litigation can overreach and collapse under its own weight, which it does here in several ways:

**The “Healthy” Claims Are Preempted By The FDCA (21 U.S.C. § 301, et seq.).**

Plaintiffs’ “healthy” claims focus on the amount of saturated fat in seven KIND bars. Significantly, however, plaintiffs do *not* challenge KIND’s labeling of the amount of saturated fat, acknowledging (as they must) that KIND “discloses the saturated fat content” per serving to the gram in the Nutrition Facts Panel on the label of each bar. Compl. ¶ 58; Giali Decl. Exs. A, B. Rather, plaintiffs’ theory of liability rests entirely on KIND’s alleged technical violation of FDA’s complex “healthy” regulation. As plaintiffs put it, KIND “does not make known that these [saturated fat] content levels exceed federal requirements[.]” Compl. ¶ 58. But where claims “exist solely by virtue of the FDCA,” as plaintiffs’ claims unquestionably do, they are preempted. *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 353 (2001). Plaintiffs’ entire theory of liability—*i.e.*, what KIND “does not make known”—vanishes if section 101.62(c)(2) did not exist.

**The “Natural” Claims Are Subject To FDA’s Primary Jurisdiction.** The Complaint also challenges “all natural” labeling on thirty-seven of KIND’s snack foods (*see* Compl. ¶ 1) based on the purported presence of “synthetic, chemically synthesized, highly processed, and/or . . . GMO[]” ingredients. *Id.*, ¶ 38. However, on November 12, 2015, FDA—the federal agency

tasked by Congress with considering and regulating on these exact issues—opened a pre-rule-making docket to obtain information and comments regarding the “Use of the Term ‘Natural’ in the Labeling of Human Food Products.” In doing so, FDA is soliciting comments and proposals from the public and food industry on the same issues raised in the Complaint:

- [W]hat *type(s) of ingredients* would disqualify the food from bearing the term [“natural”]?
- Should *the manner in which an ingredient is produced or sourced* affect whether a food containing that ingredient may be labeled as “natural?”
- [S]hould *certain production practices . . . , for example, genetic engineering*, . . . be a factor in defining “natural?” Why or why not?
- Should the term “natural” *only apply to “unprocessed” foods*? If so, *how should “unprocessed” and “processed” be defined*[?]

80 Fed. Reg. 69905, 69908 (Nov. 12, 2015) (“Request”), attached to Giali Decl. Ex. C (emphasis added). FDA has received over 3,000 responses already and will be taking comments until May 10. It then will be deciding whether “to revise [its] policy regarding use of the term “natural” or engage in rulemaking to establish a regulatory definition for ‘natural.’” *Id.*

Even before FDA’s Request, courts recognized that “natural” litigation raises “particularly complicated” labeling issues “not yet addressed by the agency,” which Congress has committed to” FDA’s sound discretion and “expertise.” *Astiana v. Hain Celestial Grp., Inc.*, 783 F.3d 753, 760 (9th Cir. 2015). Accordingly, stays of actions challenging “natural” labeling in deference to FDA’s primary jurisdiction are appropriate. *Id.*

Now, given FDA’s Request, the case for staying plaintiffs’ “natural” claims on primary jurisdiction grounds is all the more warranted and straightforward. *See Swearingen v. Late July Snacks LLC*, 2014 WL 2215878, at \*3 (N.D. Cal. May 29, 2014) (primary jurisdiction applied to false advertising claims challenging the “evaporated cane juice” ingredient, while FDA “is actively considering an issue central to the litigation”). Accordingly, these claims should be

dismissed and/or stayed pending FDA's potential rule-making regarding the use of "natural" on food labels.

Although these two grounds alone warrant dismissal of the Complaint, there are several additional, independent reasons why plaintiffs do not and cannot state a claim.

**First**, setting aside the significant issue of whether there even was a violation of federal food labeling regulations, such violations are *not* synonymous with consumer deception. All plaintiffs allege, however, is a naked violation (*i.e.*, KIND "does not make known" that its labeling allegedly fails to meet technical "federal requirements;" Compl. ¶ 58). To state a claim, plaintiffs would have to allege (at least) that they knew about the "healthy" regulations, knew what the regulations mean, materially relied on those regulations in their purchasing decisions of KIND products, and thereby assumed at the time of purchase that the products had not more than 1 gram of saturated fat per RACC. Otherwise there is no deception. Plaintiffs do not allege any of that nor could they; "[i]t is simply not plausible that consumers would be aware of [these] FDA regulations." *Mason v. Coca-Cola Co.*, 774 F. Supp. 2d 699, 705 (D.N.J. 2011).

**Second**, to even read the challenged word "healthy," plaintiffs would have had to navigate a 5-line statement in small font on the back of the wrapper. Assuming they did (a rather generous assumption), that's the same location they would encounter the Nutrition Facts Panel ***detailing precisely the "Saturated Fat" level per serving to the gram*** (Giali Decl. Exs. A, B), as plaintiffs readily acknowledge (Compl. ¶ 58). What is more, plaintiffs do not (and cannot) plausibly allege that they thought a general reference to "healthy and tasty" implicated the federal "healthy" regulation or meant that the KIND bars simply must have not "more than one gram of saturated fat per serving" because of the "healthy and tasty" statement or meant that more than 1 gram of saturated fat is a "high" level. *Id.*, ¶¶ 5, 54. Separately, plaintiffs do

not explain how they could have been fooled as to any of this when the bars plainly disclose that they contained “at least 3.5 grams of saturated fat.” *Id.*, ¶¶ 54, 58. *See Hopper v. Banana Republic, LLC*, 2008 WL 490613, at \*2 (S.D.N.Y. Feb. 25, 2008) (“statements are inherently contradictory and therefore implausible”).

***Third***, plaintiffs’ “natural” claims fail because they cannot allege that they, or any reasonable consumer, were plausibly deceived by the use of the word “natural.” Plaintiffs hitch their “natural” claims to the dictionary definition of “natural,” *i.e.*, “existing in or caused by nature; not made or caused by humankind.” Compl. ¶ 40. But plaintiffs know that KIND bars—a packaged snack food—are not “springing fully-formed from . . . trees and . . . bushes.” *Pelayo v. Nestle USA, Inc.*, 989 F. Supp. 2d 973, 978 (C.D. Cal. 2013) (“natural” allegations dismissed at pleading stage). For the same reason, plaintiffs are “also aware” that the challenged *ingredients* (not just the product as a whole) “do not come directly from plants [or] trees . . . . Thus, this definition of ‘natural’ cannot apply to the [challenged] ingredients.” *Id.* at 978 n.4.

For these reasons and the others detailed below, the Court should dismiss the Complaint, “at the point of minimum expenditure of time and money by the parties and the court.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 558 (2007).

## **II. BACKGROUND**

### **A. FDA’s “Healthy” Regulatory Scheme**

21 C.F.R. § 101.65 governs use on a food label of the term “healthy” when it is used as an “implied nutrient-content claim,” *i.e.*, if the term is used “in connection with an explicit or implicit claim or statement about a nutrient (e.g., ‘healthy,’ contains 3 grams of fat’).” *Id.*, § 101.65(d)(1)(ii). Significantly, when not used in that context, use of the word “healthy” on a food label is not constrained by § 101.65 and is not regulated as a nutrient-content claim. FDA has explained, for example, that “in the statement ‘eat lots of fruits and vegetables for a healthy

diet,’ the term ‘healthy’ does not imply the absence or presence of a nutrient *in a particular amount*, nor does it imply that the food bearing the term is particularly useful in achieving dietary recommendations.” 59 Fed. Reg. 24232, 24235 (May 10, 1994) (emphasis added).

If “healthy” *is* used in association with an express or implied claim about a specific nutrient, FDA places *seven* different restrictions on how it can be used, based on total fat levels, saturated fat levels, cholesterol levels, and other requirements that vary based on composition of the food. *See* 21 C.F.R. § 101.65(d)(2)(i)-(iv). With respect to saturated fat, FDA states:

Under section 403(r)(1)(A) of the [FDCA], a claim that characterizes the level of a nutrient which is of the type required to be in the labeling of the food must be made in accordance with a regulation authorizing the use of such a claim. ... In accordance with 21 CFR 101.65(d)(2), you may use the term ‘healthy’ as an implied nutrient content claim on the label or in the labeling of a food provided that the food, among other things, is “low saturated fat” as defined in 21 CFR 101.62(c)(2) [i.e., the food has a saturated fat content of 1 g or less per Reference Amount Customarily Consumed (RACC) and no more than 15 percent of the calories are from saturated fat].

Dkt. 52-1 at 1, 2.

Plaintiffs claim that they saw a reference to “healthy and tasty” in romance language on the back of the wrapper and interpreted it as a representation that the bars meet each of these highly technical nutrient-content requirements, and in particular, the saturated fat limits set forth in 21 C.F.R. § 101.62(c)(2). *See* Compl. ¶ 5.



**B. Plaintiffs’ Allegations And False Advertising Theory Of Liability**

On KIND bars, which make up 24 of the 37 class products, the front of the wrapper includes a statement of the products’ various attributes, which among other things, includes the statement in “ALL NATURAL / NON GMO,” above statements such as “GOOD SOURCE OF FIBER,”

“GLUTEN FREE,” and “DAIRY FREE.” *Id.*, ¶ 37; Giali Decl. Ex. B.<sup>2</sup>

On the back of the wrapper, shown at page 1, the bars contained variations on the following romance language: “Healthy *and* tasty, convenient *and* wholesome, economically sustainable *and* socially impactful.” Giali Decl. Exs. A,B; Compl. ¶ 53.<sup>3</sup>

The Nutrition Facts Panel (also featured on the back of the wrapper) conspicuously “discloses the saturated fat content” in the bars to the gram (Compl. ¶ 58), as well as other relevant facts and nutrient levels, including “Calories,” “Calories from Fat,” “Total Fat,” “Trans Fat,” “Cholesterol,” “Total Carb[ohydrates],” “Dietary Fiber,” “Sugars” and “Protein.”

<b>Nutrition Facts</b> Serv. Size 1 Bar (40g) <b>Calories</b> 190 Calories from Fat 100 <small>*Percent Daily Values (DV) are based on a 2,000 calorie diet.</small> Vit. A 0% • Vit. C 0% • Calcium 4% • Iron 4% • Vit. E 15% • Phosphorus 6% Magnesium 10% • Manganese 15%	Amount/Serving	% DV*	Amount/Serving	% DV*
	<b>Total Fat</b> 12g	<b>18%</b>	<b>Potassium</b> 150mg	<b>4%</b>
	Saturated Fat 5g	<b>25%</b>	<b>Total Carb.</b> 21g	<b>7%</b>
	Trans Fat 0g		Dietary Fiber 3g	<b>12%</b>
	<b>Cholesterol</b> 0mg	<b>0%</b>	Sugars 12g	
	<b>Sodium</b> 25mg	<b>1%</b>	<b>Protein</b> 3g	

Giali Decl. Exs. A, B.

Plaintiffs allege that they purchased challenged products “in reliance on the representations on the product labels that the products were ‘all-natural’ and had various

<sup>2</sup> The challenged product packaging is properly before the Court on this motion. *See, e.g.*, Compl., ¶ 37; *Weiss v. Inc. Vill. Of Sag Harbor*, 762 F. Supp. 2d 560, 567 (E.D.N.Y. 2011) (on motion to dismiss, court may consider documents incorporated by, or relied upon in, the complaint); *Samet v. Procter & Gamble Co.*, 2013 WL 3124647, at \*2 n.21 (N.D. Cal. June 18, 2013); *Rooney v. Cumberland Packing Corp.*, 2012 WL 1512106, at \*1-2 (S.D. Cal. Apr. 16, 2012). FDA’s Request (Giali Decl. Ex. C) is also properly before the Court. *See Nw. Env’tl. Advocates v. U.S. E.P.A.*, 537 F.3d 1006, 1026 (9th Cir. 2008); *U.S., ex rel. Fox Rx, Inc. v. Dr. Reddy’s Inc.*, 2014 WL 6750786, at \*1 (S.D.N.Y. Dec. 1, 2014).

<sup>3</sup> The Complaint also alleges that similar language was used on KIND’s website and in its former trade name “KIND Healthy Snacks.” *See* Compl. ¶¶ 26-29. Those alleged statements are immaterial to the Complaint, however, because *each plaintiff states that he or she only saw “the representations on the product labels.”* Compl., ¶¶ 9-14. *See Goldemberg v. Johnson & Johnson Consumer Cos.*, 8 F. Supp. 3d 467, 480 (S.D.N.Y. 2014) (plaintiff must allege that he saw the alleged misleading statements prior to purchase); *see also Murray v. Elations Co.*, 2014 WL 3849911, at \*8 (S.D. Cal. Aug. 4, 2014) (plaintiff could not base claims on television and internet advertisements that he did not see).

specified health characteristics.” Compl. ¶ 9 (plaintiff Short). But neither plaintiff Short nor any other plaintiff says what she believes “healthy” or “natural” meant in the context of the product and label. And no plaintiff alleges that he or she actually saw the statement “non-GMO” on the label of any purchased product. *See id.*, ¶¶ 9-14.

### **III. LEGAL ARGUMENT**

#### **A. PLAINTIFFS’ “HEALTHY” CLAIMS ARE PREEMPTED BY THE FDCA**

Plaintiffs’ “healthy” claims should be dismissed because they are preempted by the FDCA. The FDCA may not be privately enforced (21 U.S.C. § 337(a)) and, significantly, violations of the FDCA may not be used (as plaintiffs attempt to do here) as a predicate act for state-law claims.<sup>4</sup> As the Supreme Court unambiguously held in *Buckman*, 531 U.S. at 353, claims that “exist solely by virtue of the FDCA” are preempted. There is a “‘narrow gap’ through which a state-law claim must fit to escape preemption by the FDCA: ‘The plaintiff must be suing for conduct that *violates* the FDCA (or else his claim is expressly preempted by [21 U.S.C. § 343-1] . . . , but the plaintiff must not be suing *because* the conduct violates the FDCA (such a claim would be impliedly preempted under *Buckman*).’” *Perez v. Nidek Co.*, 711

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<sup>4</sup> *Reeves v. PharmaJet, Inc.*, 846 F. Supp. 2d 791, 797 (N.D. Ohio 2012) (“‘[T]he absence of a private right of action to enforce the FDCA means not only [are] private part[ies] precluded from bringing suit to enforce the provisions of the FDCA, they also ‘may not use other federal statutes or state unfair competition laws as a vehicle to bring a private cause of action that is based on violations of the FDCA.’”) (citation omitted); *Leonard v. Medtronic, Inc.*, 2011 WL 3652311, at \*7 (N.D. Ga. Aug. 19, 2011); *Verzani v. Costco Wholesale Corp.*, 2010 WL 3911499, at \*3 (S.D.N.Y. Sept. 28, 2010) (where “true purpose is to privately enforce alleged violations of the FDCA,” state-law claims for “unfair and deceptive business practices” are barred), *aff’d*, 432 F. App’x 29 (2d Cir. 2011); *In re Epogen & Aranesp Off-Label Mktg. & Sales Practices Litig.*, 590 F. Supp. 2d 1282, 1290-91 (C.D. Cal. 2008) (“[P]laintiffs may not use other federal statutes or state unfair competition laws as a vehicle to bring a private cause of action that is based on violations of the FDCA.”); *Fraker v. KFC Corp.*, 2007 WL 1296571, at \*4 (S.D. Cal. Apr. 30, 2007) (“[T]o the extent Plaintiff contends that alleged violations of the FDCA and Sherman Law give rise to viable state law claims, such claims are impliedly preempted by the FDCA”); *Animal Legal Defense Fund Boston, Inc. v. Provimi Veal Corp.*, 626 F. Supp. 278, 283 (D. Mass. 1986)) (“Massachusetts cannot confer on private persons the power to enforce a federal statute whose enforcement Congress left to federal administrative agencies. Nor can [they] enforce . . . the Massachusetts statute which parallels the FDCA, in a private action under the Massachusetts consumer protection...statute.”), *aff’d*, 802 F.2d 440 (1st Cir. 1986).

F.3d 1109, 1120 (9th Cir. 2013) (emphasis in original; quoting *In re Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1204 (8th Cir. 2010)); *see also Gelber v. Stryker Corp.*, 788 F. Supp. 2d 145, 154 (S.D.N.Y. 2011) (same). Plaintiffs’ “healthy” claims cannot navigate *Buckman*’s “narrow gap” because they arise solely from FDA’s healthy/implied nutrient-content claim regulations and would not and could not exist without them.

This is not a close call. Plaintiffs unabashedly embrace FDA’s theory from the March 17 warning letter, which, in turn, is based directly on an alleged technical violation of 21 C.F.R. § 101.65(d)(2). Compl. ¶¶ 5, 54, 60-62 (“the Healthy Products do not meet the requirements under federal law to be labeled as ‘healthy’”). Plaintiffs’ theory of deception is unquestionably and entirely derivative of an alleged FDCA violation, *i.e.*, KIND “does not make known that these content levels exceed federal requirements for use of the nutrient content claim ‘healthy’ on a food label.” *Id.* Plaintiffs’ allegation—that KIND was required to disclose that the level of saturated fats exceeded an FDCA requirement—“would not exist absent the federal regulatory scheme established by the FDCA” and is therefore preempted. *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 777 (D. Minn. 2009) (citing *Buckman*, 531 U.S. at 352-53).<sup>5</sup>

Judge McMahon’s well-reasoned decision in *Verzani v. Costco Wholesale Corp.*, 2010 WL 3911499 (S.D.N.Y. Sept. 28, 2010) *aff’d*, 432 F. App’x 29 (2d Cir. 2011), is directly on point. There, plaintiff claimed that net weight disclosures on seafood did not comply with

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<sup>5</sup> Courts applying *Buckman* to food false advertising claims have readily dismissed them. *See, e.g., Loreto v. Procter & Gamble Co.*, 515 F. App’x 576, 579 (6th Cir. 2013); *Fraker*, 2007 WL 1296571, at \*3. In *Loreto*, the Sixth Circuit addressed plaintiffs’ exact claim: “that Procter & Gamble omitted telling consumers that its products were ‘illegal,’ and . . . [t]he products were illegal, plaintiffs maintain, because their labeling did not comply with the FDCA’s requirements.” *Id.* at 579. As the court held in *Loreto*, plaintiffs’ theory “is impliedly preempted by federal law” because it “depends entirely upon an FDCA violation—*i.e.*, the *only* reason [the] products were allegedly ‘illegal’ was because they failed to comply with FDCA labeling requirements.” *Id.* (emphasis in original). *See* Compl. ¶¶ 54, 58.

federal labeling regulations (21 C.F.R. §§ 102.54 and 102.5), and “therefore Costco has engaged in a deceptive act under G.B.L. § 349.” *Id.* at \*3. However, the court held that

[t]he FDCA lacks a private right of action and therefore Verzani cannot rely on it for purposes of asserting a state-law consumer claim under G.B.L. § 349. *See* 21 U.S.C. § 337(a); *Buckman* . . . , 531 U.S. [at 349 & n. 4] . . . . ***Indeed, Verzani’s persistent allegations that Costco’s labeling . . . violates the FDCA and the [FDA’s] regulations on the labeling of “shrimp cocktails” indicates that his true purpose is to privately enforce alleged violations of the FDCA, rather than to bring a claim for unfair and deceptive business practices*** under G.B.L. § 349 . . . . As such, Verzani’s proposed G.B.L. § 349 claim premised on violations of the FDCA could not survive a motion to dismiss.

*Id.* (emphasis added).<sup>6</sup> Plaintiffs’ claims here are the same: an FDA labeling enforcement action disguised as a state-law false advertising lawsuit. What the Sixth Circuit recently held with respect to an identical legal theory (n.5, *supra*) is directly applicable and dispositive here:

The statute’s public enforcement mechanism is thwarted if savvy plaintiffs can label[,] as arising under a state law for which there exists a private enforcement mechanism[,] a claim that in substance seeks to enforce the FDCA. Under principles of “implied preemption,” therefore, private litigants may not “bring a state-law claim against a defendant when the state-law claim is in substance (even if not in form) a claim for violating the FDCA.”

*Loreto v. Procter & Gamble Co.*, 2013 WL 645952, at \*2 (6th Cir. Feb. 22, 2013).

#### **B. PLAINTIFFS’ “NATURAL” CLAIMS FALL UNDER FDA’S PRIMARY JURISDICTION**

Plaintiffs’ “natural” claims should be dismissed and/or stayed based on FDA’s primary jurisdiction. In that way, FDA will be allowed to fulfill its mandate to resolve the issue in the first instance, “maintaining uniformity in the regulation of an area entrusted to a federal agency.” *Ellis v. Tribune Television Co.*, 443 F.3d 71, 82 (2d Cir. 2006) (citation omitted); *see also* 21 C.F.R. § 10.25(b) (as between it and the judiciary, “FDA has primary jurisdiction to

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<sup>6</sup> Moreover, because the claim was preempted, the court found that it was unnecessary “to address Verzani’s arguments that the label . . . does not comply with 21 C.F.R. §§ 102.54 and 102.5.” *Verzani*, 2010 WL 3911499, \*3. As in *Verzani*, the Court here need not address whether FDA or plaintiffs allege a plausible violation of 21 C.F.R. § 101.65(d)(2).

make the initial determination on issues within its statutory mandate”). FDA’s recent Request (pages 2-3, *supra*) demonstrates that FDA is now actively involved in resolving the very labeling issues raised by plaintiffs’ “natural” claims, all of which are matters that fall “squarely” within FDA’s “expertise and discretion.” *Id.*

**1. The Ninth Circuit’s Primary Jurisdiction Analysis Of “Natural” Claims In *Astiana* Is Sound And Applies With Far Greater Force Today**

In *Astiana*, 783 F.3d at 760, the Ninth Circuit recently applied primary jurisdiction to challenges to “natural” labeling statements on cosmetics, products also within FDA’s jurisdiction. *See* 21 C.F.R. § 700.3 *et seq.* The court held that “[d]etermining what chemical compounds may be advertised as natural on cosmetic product labels is ‘a particularly complicated issue that Congress has committed to the FDA,’” and therefore, “[o]btaining expert advice from that agency would help ensure uniformity in administration of the comprehensive regime established by the FDCA.” *Astiana*, 783 F.3d at 761. The court was not troubled for a minute at that time—in April 2015—by the fact that “FDA had shown some reticence to define ‘natural’” due to “the complexities of the issue.” *Id.* Even though at the time of the *Astiana* decision FDA was on record as recognizing that “procedures for establishing the meaning of the term ‘natural’” would require “adequate public participation,” but that other pressing “health and safety matters [were] currently fully occupying the resources that FDA has available for proceedings” (*id.* at 759-60), the Ninth Circuit had no problem affirming a stay of a “natural” case under FDA’s primary jurisdiction.

Now that FDA has actually opened a formal public comment docket on “natural” labeling standards through its Request (pages 2-3, *supra*), the teachings of *Astiana* are all the more persuasive and applicable. In fact, FDA’s action is a direct response, in part, to requests made by “Federal district courts” addressing private “natural” false advertising lawsuits “for an

administrative determination under 21 CFR 10.25(c) . . . [of] whether food products containing ingredients produced using bioengineering may be labeled as ‘Natural,’ ‘All Natural,’ and/or ‘100% Natural.’” Giali Decl. Ex. C at 1.

There is an avalanche of precedent applying the primary jurisdiction doctrine to food labeling issues that FDA is in the process of considering (*e.g.*, evaporated cane juice, “0g Trans Fat” claims), and it points uniformly to deferring to FDA on the “natural” issues raised by plaintiffs so that FDA can complete its work.<sup>7</sup> In fact, the case for applying primary jurisdiction is no stronger than here given that FDA has expressly taken up “natural” labeling in direct response to the recent proliferation of “natural” lawsuits. *Id.*

## **2. There Are Additional, Compelling Reasons Why Plaintiffs’ “Natural” Claims Should Be Addressed By FDA In The First Instance**

Courts within the Second Circuit generally consider four factors in applying the primary jurisdiction doctrine:

(1) whether the question at issue is within the conventional experience of judges or whether it involves technical or policy considerations within the agency’s particular field of expertise; (2) whether the question at issue is particularly within the agency’s discretion; (3) whether there exists a substantial danger of inconsistent rulings; and (4) whether a prior application to the agency has been made.

*Ellis*, 443 F.3d at 82. FDA’s active consideration of “natural” labeling (page 2-3, *supra*) is, by itself, sufficient to satisfy these elements and weighs strongly in favor of the doctrine’s application.

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<sup>7</sup> See, *e.g.*, *Walker v. B&B Foods, Inc.*, 2016 WL 463253 (N.D. Cal. Feb. 8, 2016); *Red v. Gen. Mills, Inc.*, 2015 WL 9484398 (C.D. Cal. Dec. 29, 2015); *Backus v. Gen. Mills, Inc.*, 2015 WL 4932687 (N.D. Cal. Aug. 19, 2015) (all dismissing or staying trans fat claims); see also *Saubers v. Kashi Co.*, 39 F. Supp. 3d 1108, 1112-13 (S.D. Cal. 2014); *Swearingen v. Healthy Beverage LLC*, 2014 WL 2696719 (N.D. Cal. June 11, 2014); *Gitson v. Clover-Stornetta Farms, Inc.*, 2014 WL 2638203 (N.D. Cal. June 9, 2014); *Smedt v. The Hain Celestial Group, Inc.*, 2014 WL 2466881 (N.D. Cal. May 30, 2014) (all dismissing or staying evaporated cane juice claims).

**a. Developing A Uniform Definition For “Natural” Labeling In Food Is Uniquely Within The Purview Of FDA And Is Not Within The Conventional Experience Of Judges**

As the Ninth Circuit recognized recently, “[w]ithout doubt, defining what is ‘natural’ for cosmetics labeling is both an area within the FDA’s expertise and a question not yet addressed by the agency.” *Astiana*, 783 F.3d at 760. The same is true for defining “natural” on food labels.<sup>8</sup> In contrast, courts have recognized that they are *not* well-equipped to address the highly technical—and mixed scientific-philosophical—issues implicated by what is or is not a “natural” food. *See, e.g., Allen v. Hyland’s Inc.*, 300 F.R.D. 643, 668 (C.D. Cal. 2014) (“natural” has no “fixed meaning”); *Astiana v. Kashi Co.*, 291 F.R.D. 493, 508 (S.D. Cal. 2013) (no uniform definition of “all natural” exists among consumers); *Pelayo*, 989 F. Supp. 2d at 979 (“the term ‘natural’ can be used in numerous contexts” and “may convey different meanings depending on that context”) (citing FTC decision declining to define “natural,” 75 Fed. Reg. 63552, 63586 (Oct. 15, 2010)). FDA, the federal agency that has been tasked with the responsibility for establishing uniform labeling regulations for food such as KIND bars, is the entity that is equipped to establish a national, coherent, and uniform standard for “natural.”

**b. The Standards For Food Labeling Are Uniquely Within The FDA’s Authority And Discretion**

The reasons detailed in the prior section satisfy this requirement, too. Indeed, the Request issued by FDA (page 2-3, *supra*) is a first step towards FDA’s rulemaking on “natural” labeling for food in response to the many citizens petitions that have been filed by interested

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<sup>8</sup> *See, e.g., Coyle v. Hornell Brewing Co.*, 2010 WL 2539386, at \*4 (D.N.J. June 15, 2010) (“The use of the term ‘natural’ as it pertains to food and beverage labeling falls within the FDA’s discretion. The FDA employs food technicians, chemists, nutritionists, and numerous other specialists in order to address public health and safety issues relating to foods and numerous other specialists in order to address public health and safety issues relating to foods and medicines.”); *Cox v. Gruma Corp.*, 2013 WL 3828800, at \*2 (N.D. Cal. Jul. 11, 2013) (it is simply wrong to “conclude[] that there is no agency charged with determining whether food labels may properly state that GMO products can be labeled ‘all natural.’ The FDCA and NLEA unquestionably and squarely give that authority to the FDA.”).

parties seeking FDA’s guidance. *See* 21 C.F.R. § 10.30(h). Moreover, whether and when FDA acts to promulgate formal regulations is exactly the type of policy decision that Congress has entrusted to FDA (and USDA for meat, poultry and egg products), the regulatory body with the proper expertise to consider and make sound policy decisions about “natural” labeling on KIND products. *See* n.8, *supra*. Plaintiffs should not be able to upset FDA’s regulatory process mid-stream, particularly when FDA opened a docket on its own.

**c. There Is A Substantial Danger Of Inconsistent Rulings If Individual Courts Make “Natural” Labeling Determinations**

Allowing individual courts to make judicial determinations as to the appropriate definition for “natural” on food labels would result in a patch-work of decisions and differing requirements—on a case-by-case and product-by-product basis, no less—that would make uniform food labels impossible. It is “easy to see why Congress would not want to allow states to impose disclosure requirements of their own on packaged food products,” as “[m]anufacturers might have to print 50 different labels . . . .” *Turek v. Gen. Mills, Inc.*, 662 F.3d 423, 426 (7th Cir. 2011) (Posner, J; preemption). Permitting FDA to resolve “natural” labeling issues in the first instance “will ensure national uniformity in labeling” which is “particularly significant” where, as here, “several recently-filed . . . lawsuits throughout the country involve the same or similar issues as found in the instant suit. The increasing volume of this litigation creates the potential for inconsistent judicial rulings.” *Taradejna v. Gen. Mills, Inc.*, 909 F. Supp. 2d 1128, 1135 (D. Minn. 2012); *Swearingen*, 2014 WL 2215878, at \*3 (primary jurisdiction applied to false advertising claims challenging the “evaporated cane juice” ingredient, while FDA “is actively considering an issue central to the litigation”).

Here, if FDA determines that the challenged ingredients or GMOs *are* permitted in foods labeled “all natural,” then plaintiffs’ claims will be expressly preempted. *See* 21 U.S.C.

§ 343-1(a). If this action is not deferred, discordant rulings would (at the least) force KIND to print different labels on a jurisdiction-by-jurisdiction basis or, even worse, subject it to conflicting standards in the states covered by plaintiffs' claims. Certainly, "[t]he prospect that different labels would be permissible in different jurisdictions would impose a burden . . . that may be alleviated if the FDA chooses to speak directly to the question." *Coyle*, 2010 WL 2539386 at \*4 (staying "100% Natural" litigation on primary jurisdiction grounds). Now FDA has started the process of "speak[ing] directly to the question." *Id.*

### **3. FDA's Prior Statements On "Natural" And Court Decisions That Pre-Date FDA's Request Do Not Lead To A Different Result**

FDA's prior policy statements and decisions declining to define "natural" must yield to FDA's Request (pages 2-3, *supra*). Moreover, in light of the Request, plaintiffs' reliance on a 1993 informal, non-binding policy for natural labeling announced by FDA as "the most definitive statement of the agency's view" (Compl. ¶ 43) is misplaced. Indeed, in the Request, FDA made clear that its 1993 prior "policy concerning the use of the term 'natural,' . . . was *not intended* to address . . . the use of genetic engineering or *other forms of genetic modification*, . . . *nor did it explicitly address food processing or manufacturing methods*," *i.e.*, the 1993 policy expressly did *not* address the alleged bases for plaintiffs' "natural" claims. *See* Giali Decl. Ex. C at 1. Significantly, any court decision that pre-dates the November 12, 2015 Request and that declines to apply the primary jurisdiction doctrine to "natural" claims is not a reliable statement of the law.

### **C. THE COMPLAINT FAILS AS A MATTER OF LAW ON OTHER GROUNDS**

A complaint must be dismissed when it does not allege "enough facts to state a claim to relief that is plausible on its face." *Twombly*, 550 U.S. at 570. Plausibility is "context-specific," requiring the Court to "draw on its judicial experience and common sense." *Ashcroft v. Iqbal*,

556 U.S. 662, 679 (2009). Here, plaintiffs never connect the dots to a consumer deception claim.<sup>9</sup>

**1. Plaintiffs’ “Healthy” Claims Are Not Plausible**

**a. Plaintiffs Cannot Plausibly Show That They Were Deceived By A Hyper-Technical Violation Of FDA’s Labeling Requirements**

Plaintiffs assert that the “healthy” products are “mislabeled,” because they do not “meet the requirements for use of the term ‘healthy’ that are set forth in 21 C.F.R. [§] 101.65(d)(2).” Compl., ¶¶ 5, 54, 58. That is the *only* theory plaintiffs advance for why the “healthy” products are not, in fact, healthy. Even if plaintiffs’ theory could escape *Buckman* preemption, not every “arcane violation of FDA food labeling regulations . . . amounts to an act of consumer fraud.” *Mason*, 774 F. Supp. 2d at 705. To show actual deception and resulting injury, each plaintiff needs to allege:

- (a) they were aware of FDA’s numerous implied nutrient-content claim regulations related to “healthy,” 21 C.F.R. § 101.65 *et seq.*;
- (b) they read the small print on the back “Healthy *and* tasty, convenient *and* wholesome, economically sustainable *and* socially impactful” (*see* Giali Decl. Ex. A), and concluded that it was “an explicit or implicit claim or statement about a nutrient,” 21 C.F.R. § 101.65(d)(1)(i), triggering the “low saturated fat” requirement in 21 C.F.R. § 101.62(c)(2); and
- (c) concluded, in accordance with § 101.62(c)(2), that the products should contain “1 g or less of saturated fatty acids per reference amount customarily consumed and not more than 15 percent of calories from saturated fatty acids.”

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<sup>9</sup> Under each of the consumer protection laws of California, Florida, Illinois, and New York, plaintiffs must plausibly allege, at a minimum, that they were deceived by the challenged advertising, resulting in an actual injury to money or property. *See, e.g., McLaughlin v. Am. Tobacco Co.*, 522 F.3d 215, 226-27 (2d Cir. 2008) (GBL § 349); *Avola v. Louisiana-Pacific Corp.*, 991 F. Supp. 2d 381, 396-97 (E.D.N.Y. 2013) (GBL § 350); *Williamson v. Reinalt-Thomas Corp.*, 2012 WL 1438812, at \*8 (N.D. Cal. Apr. 25, 2012) (UCL, FAL, and CLRA); *Kais v. Mansiana Ocean Residences, LLC*, 2009 WL 825763, at \*2 (S.D. Fla. Mar. 26, 2009) (FDUTPA); *Oshana v. Coca-Cola Co.*, 472 F.3d 506, 513-14 (7th Cir. 2006) (ICFA). Absent plausible deception, plaintiffs’ common-law claims fail, as well. *See, e.g., DiMuro v. Clinique Labs., LLC*, 572 F. App’x 27, 32 (2d Cir. 2014); *Derbaremdiker v. Applebee’s Int’l, Inc.*, 2012 WL 4482057, at \*8 (E.D.N.Y. Sept. 26, 2012).

Plaintiffs allege none of that. As in *Mason*, they allege (Compl. ¶¶ 9-14) merely “that they thought they were buying a ‘healthy’ product that happened to apparently run afoul of FDA regulations.” *Mason*, 774 F. Supp. 2d at 705. That does not establish “a cognizable and compensable harm” and a private right to sue for false advertising, because “[i]t is simply not plausible that consumers would be aware of FDA regulations regarding ‘nutrient content’ [claims],” much less the particulars of FDA’s highly technical definition of “low saturated fat.” *Id.* at 705 n.4. Numerous courts from across the country have held the same.

Victor still fails to plead with particularity how precisely a reasonable consumer would be misled by the term “delivers healthful antioxidants” ***or what exactly is misleading about it aside from the fact that it may technically violate FDA regulations.*** A statement may technically violate some law and yet a reasonable consumer may have no dashed expectation about it. . . . ***Indeed, Victor’s expectation is unreasonable as a matter of law because no reasonable consumer would expect that every product on the market conforms with all applicable laws—to hold otherwise would subject defendants to fraud claims even for arcane, minute, immaterial, or technical violations of certain laws.***

*Victor v. R.C. Bigelow, Inc.*, 2014 WL 1028881, at \*17 (N.D. Cal. Mar. 14, 2014) (emphasis added); *Gitson v. Trader Joe’s Co.*, 2015 WL 9121232, at \*2 (N.D. Cal. Dec. 1, 2015) (dismissing consumer claims based on soymilk name technically violating FDA’s standard of identity for milk because the reasonable consumer is not deceived into thinking soymilk comes from a cow); *Bishop v. 7-Eleven, Inc.*, 37 F. Supp. 3d 1058, 1066 (N.D. Cal. 2014) (dismissing consumer deception claims based on technical violation of FDA regulations); *Thomas v. Costco Wholesale Corp.*, 2014 WL 1323192, at \*5-6 (N.D. Cal. Mar. 31, 2014) (same).

#### **b. KIND’s “Healthy” Labeling Is Not Deceptive**

Even if plaintiffs allege their own deception, false advertising claims must be dismissed where, as here, the Court “can conclude as a matter of law that members of the public are not likely to be deceived by the product packaging.” *Pelayo*, 989 F. Supp. 2d at 978; *accord Leider*

*v. Ralfe*, 387 F. Supp. 2d 283, 292 (S.D.N.Y. 2005).<sup>10</sup> To be sure, plaintiffs recite the conclusion that “[n]o reasonable consumer would believe that bars high in saturated fat are ‘healthy’” (Compl. ¶ 56), but plaintiffs fail to define what they or a reasonable consumer understands is a “high” amount of saturated fat or how and why consumers would transform “healthy and tasty” into a technical specification of “1 g or less of saturated fatty acids per reference amount customarily consumed and not more than 15 percent of calories from saturated fatty acids.” 21 C.F.R. § 101.62(c)(2)(i).

Instead, as recognized by the current U.S. Government’s Dietary Guidelines for Americans (“Dietary Guidelines”), consumers do not “eat food groups and nutrients in isolation but rather in combination, and the totality of the diet forms an overall eating pattern.” *See* <http://health.gov/dietaryguidelines/2015/guidelines/executive-summary/> (visited March 7, 2016). Consumers understand that unhealthy foods (*e.g.*, candy, soda) can be free of saturated fat, whereas many universally-recognized healthy foods (*e.g.*, seeds, nuts, and salmon, each of which is recommended for *increased* consumption by the Dietary Guidelines) may contain saturated fat levels well in excess of the limits prescribed by 21 C.F.R. § 101.62(c)(2)(i). The Dietary Guidelines focus on the *overall* nutritional quality of the diet and types of foods that people should eat, with less consideration given to specific nutrient levels in each individual food that people consume. They state, for example, that a “healthy eating pattern” includes

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<sup>10</sup> This is a purely “objective” standard, “whereby deceptive acts or practices . . . are ‘limited to those likely to mislead a reasonable consumer acting reasonably under the circumstances.’” *Leider*, 387 F. Supp. 2d at 292 (quoting *Oswego Laborers’ Local 214 Pension Fund v. Marine Midland Bank, N.A.*, 85 N.Y.2d 20, 26 (1995)). Claims brought under the CLRA, UCL, and FAL (California), the ICFA (Illinois), and the FDUTPA (Florida) are subject to the same objective standard. *See McKinniss v. Gen. Mills, Inc.*, 2007 WL 4762172, at \*2 (C.D. Cal. Sept. 18, 2007); *F.T.C. v. Bay Area Bus. Council, Inc.*, 423 F.3d 627, 635 (7th Cir. 2005); *In re Michaels Stores Pin Pad Litig.*, 830 F. Supp. 2d 518, 525-26 (N.D. Ill. 2011); *Zlotnick v. Premier Sales Grp., Inc.*, 480 F.3d 1281, 1284 (11th Cir. 2007). Similarly, plaintiffs’ common-law claims require them to show *reasonable* reliance on the challenged advertising. *See Avola v. Louisiana-Pac. Corp.*, 991 F. Supp. 2d 381, 391 (E.D.N.Y. 2013); *Orlando v. Kukielka*, 40 A.D.3d 829, 831 (2007).

“nuts, seeds.” *Id.* at Ch. 1, “Key Recommendations.” In other words, Americans should focus on constructing healthy eating patterns that are rich in recommended food groups containing nutrient-dense foods.

Significantly, *nuts and seeds are the principal source of saturated fat in KIND’s products*. Giali Decl., Ex. A, B. Indeed, plaintiffs’ conception of “healthy” would prohibit its use in reference to products like almonds, avocados, and salmon based solely on their saturated fat levels—regardless of what other health benefits they provide. Compl. ¶ 63. Instead, plaintiffs’ definition of “healthy” would encompass foods such as low fat chocolate pudding and certain sugary children’s cereals. Plaintiffs’ notion of “healthy” has no basis in ordinary consumers’ understanding or what a consumer would find useful in establishing a healthy diet.

Regardless, even if plaintiffs and reasonable consumers understood the term “healthy” in a manner consistent with the FDA regulations, neither plaintiffs nor a reasonable consumer could have been plausibly misled by the “healthy and tasty” statement on the product labels because it is located on the back of the wrapper, along with the Nutrition Facts Panel that provides objective and *specific* disclosures of the exact amount of “Saturated Fat,” “Total Fat,” “Trans Fat,” and “Calories from Fat.” Giali Decl. Ex. A, B. No reasonable consumer reads “healthy and tasty” and makes an inferential leap to “low saturated fat,” much less “one gram or less” (*id.*, ¶ 54), when *the exact amount* of “Saturated Fat” is disclosed by the Nutrition Facts Panel *on the same side of the product* as the challenged “healthy” statement. *Id.*, ¶ 58; Giali Decl. Ex. A.

Taken in context with the entire label, which shows consumers the *specific* level of saturated fat in each product, a single reference to the fanciful statement “healthy *and* tasty” in small print on the back is “simply too vague for a reasonable consumer to rely on it in any

material way.” *Leonard v. Abbott Labs., Inc.*, 2012 WL 764199, at \*22 (E.D.N.Y. Mar. 5, 2012); *see also Gitson*, 2015 WL 9121232, at \*1 (rejecting claim that “soymilk” implied “similar nutritional content to cow’s milk,” because “if the consumer cared about the nutritional content, she would consult the label”); *Verzani*, 2010 WL 3911499, at \*2 (rejecting claim that “a reasonable consumer would believe that the weight disclosure on the label ... refers only to the shrimp (and not the other ingredients in the package)”); even if required by FDA, “a simple visual inspection of the tray . . . reveals that shrimp is not the only edible item inside”).

It is entirely appropriate and warranted, then, for this Court to “expect[]” that consumers, if they cared, “would . . . peruse the product’s contents simply by reading the” label in order to provide context-specific meaning to KIND’s “healthy *and* tasty” labeling statement. *McKinnis v. Gen. Mills, Inc.*, 2007 WL 4762172, at \*3 (C.D. Cal. Sept. 18, 2007); *Viggiano v. Hansen Natural Corp.*, 2013 WL 2005430, at \*9 n.38 (C.D. Cal. May 13, 2013) (same).

## **2. Plaintiffs’ “Natural” Claims Are Not Plausible**

Neither FDA (yet) nor FTC has established a definition of “natural” in the context of food labeling and advertising. In its Request, FDA asked for public comment on at least sixteen distinct and highly-technical issues involving natural labeling, and has received *thousands* of submissions from scientific, industry, and consumer groups offering analysis and proposals for “natural.” Despite this uncertainty and lack of uniformity among food experts, plaintiffs glibly contend that consumers such as themselves rely on the New Oxford American Dictionary definition of “natural,” to claim that an “all natural” labeling statement is a “represent[ation] that ‘the whole quality [and] extent’ of the ingredients . . . ‘[exist] in or [are] caused by nature; not made or caused by humankind.’” Compl. ¶ 41. But the literal dictionary meaning of “natural” is not plausible for a packaged snack food sold on the shelves of retail stores across the country.

Plaintiffs admit they knew that they were buying a packaged “snack food” (*id.*, ¶ 1) at places across the country like Starbucks, yoga studios in Manhattan, and Target (*id.*, ¶¶ 9, 10, 12). And like all consumers, plaintiffs knew that the ingredients in a packaged snack food do not “spring[ ] fully-formed” from “trees” and “bushes.” *Pelayo*, 989 F. Supp. 2d at 978 (rejecting substantially similar definition “of ‘natural,’ meaning ‘produced or existing in nature’ and ‘not artificial or manufactured,’” as neither “objective” nor “plausible”). Indeed, FDA itself has previously explained that “[f]rom a food science perspective,” no food is literally “natural” because “the food has probably been processed and is no longer the product of the earth.” *See* <http://www.fda.gov/AboutFDA/Transparency/Basics/ucm214868.htm> (visited Mar. 5, 2016). It is unsurprising, then, that plaintiffs never identify a packaged food that could use the labeling statement “natural” in compliance with their definition of the term.

**a. Plaintiffs’ Alternative Definitions Are Also Implausible**

Recognizing the serious problem with claiming that a manufactured, packaged snack food is falsely represented as “existing in or caused by nature” and “not made or caused by humankind,” plaintiffs alternatively tick through several internally inconsistent definitions, without landing on any of them. *See* Compl. ¶¶ 43-48. In any event, none works as a plausible and objective meaning of “natural” capable of supporting false advertising claims.

**(1) FDA’s 1993 Policy Statement**

FDA’s 1993 policy statement on “natural” stated that FDA would take no enforcement action with respect to the term on food labels if “nothing artificial or synthetic . . . has been included in, or has been added to, a food that would not normally be expected to be in the food.” 58 Fed. Reg. 2302, 2407 (Jan. 6, 1993). Plaintiffs do not allege, nor could they, how any of the challenged “natural” ingredients are “artificial” or “synthetic,” or “would not normally be expected” to be in a processed snack bar. *See Brazil v. Dole Packaged Foods LLC*, 2014 WL

6901867, at \*5 (N.D. Cal Dec. 8, 2014). Moreover, FDA’s Request, clearly the most recent guidance on natural labeling, makes clear that none of its prior statements were intended to address GMOs or “food processing or manufacturing methods.” Giali Decl. Ex. C at 2.

### (2) “Natural” Labeling For Meat And Poultry

Plaintiffs reference standards for “natural” related to USDA’s Food Safety and Inspection Service (Compl. ¶ 44) but never explain how USDA standards, which apply to labeling of meat, poultry, and eggs, relate to a snack bar containing none of those ingredients and not under USDA’s definition. Plaintiffs also fail to allege that they were even aware of USDA’s standards for “natural,” much less that they adopted the standards in the context of their purchasing decisions.

### (3) USDA Certified “Organic”

Next, plaintiffs cite the definition of “nonsynthetic” in USDA’s National Organic Program regulations. *See* Compl. ¶ 47 (citing 7 C.F.R. § 205.1 *et seq.*). But nearly all of the challenged ingredients (including glucose, glycerin, vitamins used for enrichment or fortification, ascorbic acid, tocopherols, and pectin) are expressly *allowed* in certified “Organic” foods. *See* 7 C.F.R. §§ 205.603, 205.605, and 205.606. Moreover, consumers generally conflate organic with natural and hold organic products to a higher standard than products labeled “natural,” meaning that ingredients that are eligible for organic labeling would certainly satisfy a consumer’s expectation with respect to natural labeling. *Pelayo*, 989 F. Supp. 2d at 979; *see also Astiana v. Kashi Co.*, 291 F.R.D. 493 (S.D. Cal. 2013) (same).

### (4) GMOs

To the extent that plaintiffs assert a sub-theory to their “natural” claims premised on GMOs (*see* Compl. ¶ 42), FDA has determined that “foods derived from [GMO] sources . . . do not present any different or greater safety risks *or otherwise differ from other foods in any*

*meaningful or uniform way.*” Letter Decision, FDA Docket No. 2011-P-0723 (Nov. 19, 2015), p. 25 (emphasis added).<sup>11</sup> And, to the extent plaintiffs assert a separate challenge to the alleged “NON-GMO” labeling itself, plaintiffs lack standing to sue on that claim because no plaintiff alleges that he or she actually saw or read the “NON-GMO” labeling statement prior to purchasing the products. *See Goldemberg*, 8 F. Supp. 3d at 480.

While plaintiffs allege that “testing has detected the presence of GMOs in at least *some* of the Products,” Compl. ¶ 38 (emphasis added), they do not allege in how many of the products, the levels of GMOs detected, or, more importantly, that testing detected the presence of GMOs in any of the products they purchased.<sup>12</sup> Similarly, plaintiffs’ assertion that “approximately 90% of canola, 89% of corn, and 94% of soybeans grown in the United States are genetically modified” (Compl. ¶ 49) is insufficient as a matter of law because plaintiffs do not allege that any of the challenged “natural” ingredients used by KIND were sourced from genetically modified crops. *Gallagher v. Chipotle Mexican Grill, Inc.*, 2016 WL 454083, at \*2 (N.D. Cal. Feb. 5, 2016) (not sufficient to generally plead certain products may contain GMOs without showing that the challenged product actually contained GMOs).

Plaintiffs’ lack of detail cannot be by accident, but it is fatal to their allegations. The plausibility threshold requires “more than a sheer possibility.” *Iqbal*, 556 at 678; *see also Wallace v. ConAgra Foods, Inc.*, 747 F.3d 1025, 1030 (8th Cir. 2014) (dismissal appropriate for

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<sup>11</sup> See <http://www.regulations.gov/#!documentDetail;D=FDA-2011-P-0723-0788> (visited March 5, 2016). These findings were made by FDA in a formal letter decision and are therefore entitled to substantial *Chevron* deference. *See, e.g., Mylan Labs., Inc. v. Thompson*, 389 F.3d 1272, 1280 (D.C. Cir. 2004); *Otsuka Pharm. Co. v. Burwell*, 2015 WL 3442013, at \*7 (D. Md. May 27, 2015).

<sup>12</sup> Industry leading standards for “Non-GMO” certification expressly permit “at least some of the Products” (Compl. ¶ 38) to contain GMOs (*e.g.*, 0.9%)—in recognition of the fact that it is not realistically possible to eliminate *any* trace of GMOs from commercially available crops and seeds. *See* <http://www.nongmoproject.org/wp-content/uploads/Non-GMO-Project-Standard.pdf> (Non-GMO Project Standard IV.A.1) (visited March 5, 2016).

lack of Article III standing where plaintiffs could not show product they purchased was non-kosher beef). Accordingly, even if plaintiffs alleged that they actually saw the challenged non-GMO labeling, they would *still* lack standing because they do not allege that the products they purchased contained GMOs. *In re Whole Foods Mkt. Grp., Inc. Overcharging Litig.*, 2016 WL 852796 at \*9 (S.D.N.Y. Mar. 1, 2016) (“a claim based only on probabilistic evidence of injury, devoid of any factual allegations particular to the plaintiff and without a basis to plausibly infer that all covered products were implicated, does not adequately plead injury-in-fact”).

**b. Reasonable Consumers Do Not Share Plaintiffs’ Idiosyncratic And Conflicting Definitions Of “Natural”**

Consistent with FDA’s prior reluctance to establish standards for “natural” labeling, courts roundly recognize that “natural” labeling is inherently subjective and has no “fixed meaning.” *Allen*, 300 F.R.D. at 668. That alone warrants dismissal of plaintiffs’ “natural” claims under the reasonable consumer test—if “natural” has no fixed meaning, then it cannot be “material.” *See Leonard*, 2012 WL 764199, at \*22. Further, if reasonable consumers interpret “natural” to mean anything at all, it is *not* that packaged snack foods are “existing in or caused by nature” and “not made or caused by humankind.” Compl. ¶¶ 40-41; *Pelayo*, 989 F. Supp. 2d at 980. Nor do consumers equate “natural” with “non-GMO” (Compl. ¶ 42), which are two *separate* statements on the label (*see id.*, ¶ 37; Giali Decl. Ex. A), look to USDA’s guidelines for “natural” labeling on meat and poultry when they are not buying meat or poultry (*id.*, ¶ 44), or reference USDA’s guidelines for certified “organic” products for the meaning of “natural” (*id.*, ¶ 47).

**IV. CONCLUSION**

For all the foregoing reasons, the Complaint should be dismissed with prejudice.

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Respectfully Submitted,

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